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EXAMINER	
ROMEO, D	
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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/263,022	Applicant(s) McCarthy
	Examiner David Romeo	Art Unit 1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *5 Mar 1999* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-22* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-7, 12, to the extent that they are drawn to a polynucleotide encoding the amino acid sequence of SEQ ID NO: 2, classified in class 536, subclass 23.5.

II. Claims 1-7, 12, to the extent that they are drawn to a polynucleotide encoding the amino acid sequence of SEQ ID NO: 5, classified in class 536, subclass 23.5.

III. Claims 1-7, 12, to the extent that they are drawn to a polynucleotide encoding the amino acid sequence of SEQ ID NO: 8, classified in class 536, subclass 23.5.

IV. Claims 1-7, 12, to the extent that they are drawn to a polynucleotide encoding the amino acid sequence of SEQ ID NO: 14, classified in class 536, subclass 23.5.

V. Claims 1-7, 12, to the extent that they are drawn to a polynucleotide encoding the amino acid sequence of SEQ ID NO: 21, classified in class 536, subclass 23.5.

VI. Claims 8-10, to the extent that they are drawn to a polypeptide comprising the amino acid sequence of SEQ ID NO: 2, classified in class 530, subclass 350.

VII. Claims 8-10, to the extent that they are drawn to a polypeptide comprising the amino acid sequence of SEQ ID NO: 5, classified in class 530, subclass 350.

VIII. Claims 8-10, to the extent that they are drawn to a polypeptide comprising the amino acid sequence of SEQ ID NO: 8, classified in class 530, subclass 350.

IX. Claims 8-10, to the extent that they are drawn to a polypeptide comprising the amino acid sequence of SEQ ID NO: 14, classified in class 530, subclass 350.

X. Claims 8-10, to the extent that they are drawn to a polypeptide comprising the amino acid sequence of SEQ ID NO: 21, classified in class 530, subclass 350.

XI. Claim 11, to the extent that it/they is/are drawn to an antibody that binds a polypeptide comprising the amino acid sequence of SEQ ID NO: 2, classified in class 530, subclass 387.1.

XII. Claim 11, to the extent that it/they is/are drawn to an antibody that binds a polypeptide comprising the amino acid sequence of SEQ ID NO: 5, classified in class 530, subclass 387.1.

XIII. Claim 11, to the extent that it/they is/are drawn to an antibody that binds a polypeptide comprising the amino acid sequence of SEQ ID NO: 8, classified in class 530, subclass 387.1.

XIV. Claim 11, to the extent that it/they is/are drawn to an antibody that binds a polypeptide comprising the amino acid sequence of SEQ ID NO: 14, classified in class 530, subclass 387.1.

XV. Claim 11, to the extent that it/they is/are drawn to an antibody that binds a polypeptide comprising the amino acid sequence of SEQ ID NO: 21, classified in class 530, subclass 387.1.

XVI. Claims 13, 14, 19, 20, to the extent that it/they is/are drawn to a measuring or testing process involving antigen-antibody binding involving a polypeptide comprising the amino acid sequence of SEQ ID NO: 2, classified in class 435, subclass 7.1.

XVII. Claims 13, 14, 19, 20, to the extent that it/they is/are drawn to a measuring or testing process involving antigen-antibody binding involving a polypeptide comprising the amino acid sequence of SEQ ID NO: 5, classified in class 435, subclass 7.1.

XVIII. Claims 13, 14, 19, 20, to the extent that it/they is/are drawn to a measuring or testing process involving antigen-antibody binding involving a polypeptide comprising the amino acid sequence of SEQ ID NO: 8, classified in class 435, subclass 7.1.

XIX. Claims 13, 14, 19, 20, to the extent that it/they is/are drawn to a measuring or testing process involving antigen-antibody binding involving a polypeptide comprising the amino acid sequence of SEQ ID NO: 14, classified in class 435, subclass 7.1.

XX. Claims 13, 14, 19, 20, to the extent that it/they is/are drawn to a measuring or testing process involving antigen-antibody binding involving a polypeptide

comprising the amino acid sequence of SEQ ID NO: 21, classified in class 435, subclass 7.1.

XXI. Claim 15, to the extent that it/they is/are drawn to an indeterminate compound that binds a polypeptide comprising the amino acid sequence of SEQ ID NO: 2, indeterminate class and subclass.

XXII. Claim 15, to the extent that it/they is/are drawn to an indeterminate compound that binds a polypeptide comprising the amino acid sequence of SEQ ID NO: 5, indeterminate class and subclass.

XXIII. Claim 15, to the extent that it/they is/are drawn to an indeterminate compound that binds a polypeptide comprising the amino acid sequence of SEQ ID NO: 8, indeterminate class and subclass.

XXIV. Claim 15, to the extent that it/they is/are drawn to an indeterminate compound that binds a polypeptide comprising the amino acid sequence of SEQ ID NO: 14, indeterminate class and subclass.

XXV. Claim 15, to the extent that it/they is/are drawn to an indeterminate compound that binds a polypeptide comprising the amino acid sequence of SEQ ID NO: 21, indeterminate class and subclass.

XXVI. Claims 16, 17, to the extent that it/they is/are drawn to a measuring or testing process involving a polynucleotide encoding the amino acid sequence of SEQ ID NO: 2, classified in class 435, subclass 6.

XXVII. Claims 16, 17, to the extent that it/they is/are drawn to a measuring or testing process involving a polynucleotide encoding the amino acid sequence of SEQ ID NO: 5, classified in class 435, subclass 6.

XXVIII. Claims 16, 17, to the extent that it/they is/are drawn to a measuring or testing process involving a polynucleotide encoding the amino acid sequence of SEQ ID NO: 8, classified in class 435, subclass 6.

XXIX. Claims 16, 17, to the extent that it/they is/are drawn to a measuring or testing process involving a polynucleotide encoding the amino acid sequence of SEQ ID NO: 14, classified in class 435, subclass 6.

XXX. Claims 16, 17, to the extent that it/they is/are drawn to a measuring or testing process involving a polynucleotide encoding the amino acid sequence of SEQ ID NO: 21, classified in class 435, subclass 6.

XXXI. Claim 18, to the extent that it/they is/are drawn to an indeterminate compound that binds a polynucleotide encoding the amino acid sequence of SEQ ID NO: 2, indeterminate class and subclass.

XXXII. Claim 18, to the extent that it/they is/are drawn to an indeterminate compound that binds a polynucleotide encoding the amino acid sequence of SEQ ID NO: 5, indeterminate class and subclass.

XXXIII. Claim 18, to the extent that it/they is/are drawn to an indeterminate compound that binds a polynucleotide encoding the amino acid sequence of SEQ ID NO: 8, indeterminate class and subclass.

XXXIV. Claim 18, to the extent that it/they is/are drawn to an indeterminate compound that binds a polynucleotide encoding the amino acid sequence of SEQ ID NO: 14, indeterminate class and subclass.

XXXV. Claim 18, to the extent that it/they is/are drawn to an indeterminate compound that binds a polynucleotide encoding the amino acid sequence of SEQ ID NO: 21, indeterminate class and subclass.

XXXVI. Claims 21, 22, to the extent that it/they is/are drawn to biospecific ligand binding assay involving a polypeptide comprising the amino acid sequence of SEQ ID NO: 2, classified in class 436, subclass 501.

XXXVII. Claims 21, 22, to the extent that it/they is/are drawn to biospecific ligand binding assay involving a polypeptide comprising the amino acid sequence of SEQ ID NO: 2, classified in class 436, subclass 501.

XXXVIII. Claims 21, 22, to the extent that it/they is/are drawn to biospecific ligand binding assay involving a polypeptide comprising the amino acid sequence of SEQ ID NO: 2, classified in class 436, subclass 501.

XXXIX. Claims 21, 22, to the extent that it/they is/are drawn to biospecific ligand binding assay involving a polypeptide comprising the amino acid sequence of SEQ ID NO: 2, classified in class 436, subclass 501.

XL. Claims 21, 22, to the extent that it/they is/are drawn to biospecific ligand binding assay involving a polypeptide comprising the amino acid sequence of SEQ ID NO: 2, classified in class 436, subclass 501.

2. The inventions are distinct, each from the other because of the following reasons:

a. Each of the polynucleotides of Inventions I-V are related to each of the polypeptides of Inventions VI-X, respectively, by virtue of encoding same. The polynucleotide has utility for the recombinant production of the polypeptide in a host cell. Although the polynucleotide and polypeptide are related since the polynucleotide encodes the specifically claimed polypeptide, they are distinct inventions because they are physically and functionally distinct chemical entities, and the polypeptide product can be made by another and materially different process, such as by synthetic polypeptide synthesis or purification form the natural source. Further, the polynucleotide may be used for processes other than the production of the polypeptide, such as a nucleic acid hybridization assay.

b. Each of the polynucleotides of inventions I-V and each of the antibodies of Inventions XI-XV, respectively, are related by virtue of the polypeptide that is encoded by the polynucleotide and necessary for the production of the antibody. However, the polynucleotide itself is not necessary for antibody production and both are wholly different compounds having different compositions and functions. Therefore, these inventions are distinct.

c. The following pairwise combinations of products and methods are independent and distinct, wherein the respective products may neither be produced by, nor used in the respective methods: each of I-V and each of XVI-XX, XXVI-XL; each of VI-X and each of XXVI-XXX; each of XI-XV and each of XXVI-XXX; each of XXI-XXV and each of XVI-XX, XXVI-XXX, XXXVI-XL; each of XXXI-XXXV and each of XXVI-XXX; each of XXXI-XXXV and each of XXXVI-XL.

d. The following pairwise combinations of products are independent and distinct, wherein neither member of a pair is required for the production or use of the other, and wherein each of the pair can be manufactured independently of the other and used for independent and distinct purposes: each of I-V and each of XXI-XXV, XXXI-XXXV; each of VI-X and each of XXI-XXV, XXXI-XXXV; each of XI-XV and each of XXI-XXV, XXXI-XXXV; each of XXI-XXV and each of XXXI-XXXV.

e. Each of Inventions I-V and each of Inventions XXVI-XXX, respectively, are related as product and process of use. The inventions can be shown to be distinct if either or both

of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case each of I-V could be used for the recombinant production of the encoded polypeptide.

f. Each of the polypeptides of inventions VI-X are related to each of the antibodies of Inventions XI-XV by virtue of being the cognate antigen, necessary for the production of the antibody. Although the polypeptide and antibody are related due to the necessary stearic complementarity of the two, they are distinct inventions because they are physically and functionally distinct chemical entities, and because the polypeptide can be used in another materially different process from the use for production of the antibody, such as in a pharmaceutical composition in its own right, or in assays for the identification of agonists or antagonists.

g. Each of Inventions VI-X and each of Inventions XVI-XX, respectively, are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case each of VI-X could be used in XXXVI-XL.

h. Each of Inventions VI-X and each of Inventions XXXVI-XL, respectively, are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case each of VI-X could be used in XVI-XX.

i. Each of Inventions XI-XV and each of Inventions XVI-XX, respectively, are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case each of XI-XV could be used in XXXVI-XL.

j. Each of Inventions XI-XV and each of Inventions XXXVI-XL, respectively, are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case each of XI-XV could be used in XVI-XX.

k. The following pairwise combinations of methods are independent and distinct, wherein each member of a pair performs different functions, using different starting materials and/or process steps and/or with different outcomes: each of XVI-XX and each of XXVI-XXX, XXXVI-XL; each of XXVI-XXX and each of XXXVI-XL.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

4. Because these inventions are distinct for the reasons given above and the searches required are not coextensive, restriction for examination purposes as indicated is proper.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (703) 305-4050. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 6:45 A.M. TO 3:15 P.M.

IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, GARY KUNZ, CAN BE REACHED ON (703) 308-4623.

OFFICIAL PAPERS FILED BY FAX SHOULD BE DIRECTED TO (703) 308-4242.

FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (703) 308-0294.

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.

DAVID ROMEO
PRIMARY EXAMINER
ART UNIT 1647

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MAY 7, 2001